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APPLICATION NO.	FILIN	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/044,375	01/	10/2002	John Lawrie	14263	8264	
25763	7590	09/09/2003	,			
DORSEY &			EXAMINER PASCUA, JES F			
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MINNEAPC	LIS, MN 5	5402-1498		ART UNIT	PAPER NUMBER	
				3727		
				DATE MAILED: 09/09/2003	/1	

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.   Applicating   Application No.   DOWALD   Application   DOWALD   DO									
Examiner   Jes. F. Pascus   3727		Application No.	A	pplicant(s)					
Jes F. Pascua   3727		10/044,375	LA	WRIE ET AL.					
The MALING DATE of this communication appears on the cover sheet with the correspondence address Period for Repty  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of ten may be available under the provisions of 3 CFR 1.13(a), in no eveal, however, may a reply be timely field  ### This period for reply appelled above is less than thirty (30) stoys, as neply within the statistical for reply appelled above is less than thirty (30) stoys, as reply within the same interest of the period for reply appelled above is less than thirty (30) stoys, as reply within the same interest of the period for reply will, by databately period will appelled any evidence and period for reply appelled for reply will, by databately period will appelled the reply within the set or extended period for reply will, by databately period will appelled for reply appelled for reply appelled for reply will, by databately period will appelled the reply will be considered finely.  ### This period for reply is appelled show the mainting adds of this communication.  ### Responsive to communication(s) filed on 29 July 2003.  ### Responsive to communication is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under £x parte Queryle, 1935 C.D. 11, 453 O.G. 213.  ### Disposition of Claims  ### Allow Claim(s)	Office Action Summary	Examiner	Ar	t Unit					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Electrosistics of time may be available under the prevalence of 37 CFR 1.136(a). In an event, however, may a repty be timely fired.  Electrosistic of time may be available under the prevalence of 37 CFR 1.136(a). In an event, however, may a repty be timely fired.  Electrosistic of time the provision of the prevalence of 37 CFR 1.136(a). In an event, however, may a repty be timely fired.  Electrosistic of timely periodic abover, the maximum statutory period will apply and will expire SIX (b) MONTHS from the mailing date of this communication. Plants to the prevalence of the statutory maintained of the statutory maintained patient term adjustment. See 37 CFR 1.744(b).  Status  1) ☑ Responsive to communication(s) filled on 29 July 2003.  2a) ☑ This action is FINAL. 2b) ☐ This action is non-final.  3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parts Quayrie, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) ☑ Claim(s) is/are pending in the application.  4a) Of the above claim(s) is/are epiced to.  5) ☐ Claim(s) is/are allowed.  6) ☑ Claim(s) are subject to restriction and/or election requirement.  Application Papers  9) ☐ The specification is objected to by the Examiner.  10) ☑ The drawing(s) filed on 10 January 2002 is/are: a) accepted or b) objected to by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) ☐ The oath or declaration is objected to by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) ☐ The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. § 119 and 120  13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ The certified copies of the priority documents h									
THE MAILING DATE OF THIS COMMUNICATION.  Edeficious of time may be available under the provisions of 3 CPR 1.15(g). In no event, however, may a reply be timely filed after SX (g) MONTRS from the mailing date of this communication.  It No period for reply is specified or the provision of the communication.  It No period for reply is specified developed the mailing date of this communication.  Fallure is reply within the set of ordended period for reply will, by statute, cause the application to become ARANDONED (gs U.S.C. § 133).  Any reply received by the Official or the firm thin their membra deprived will be provided by the Office did with the three mailing date of this communication, even if timely lifed, may reduce any  Status  1) Responsive to communication(s) filed on 29 July 2003.  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-5 and 7-46 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  5) Claim(s) 1-5 and 7-46 is/are rejected.  7) Claim(s) is/are allowed.  8) Claim(s) 1-5 and 7-46 is/are rejected to.  8) Claim(s) 1-5 and 7-46 is/are rejected to.  8) Claim(s) may are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 10 January 2002 is/are: all accepted or b objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawings correction filed on 29 July 2003 is: a) particular provised by the Examiner.  If approved, corrected drawings are required in reply to this office action.  12) The eath or declaration is objected to by the Examiner.  12) All by Some * c) None of:  1. Certified copies of the priority documents have been received		pears on the cover s	heet with the corre	espondence address	; <b></b>				
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### **DETAILED ACTION**

## **Drawings**

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the method step of "forming a column" (claim 15), the method step of "forming a removable section" (claim 19), the method step of "forming a second piercing point" (claim 20), "single panel that is folded prior to the first surface being sealed to the second surface" (claim 23), the method step of "forming a compartment and a column" (claim 34), the first and second flexible surfaces being "part of a single flexible panel" (claim 35), the method step of "providing a cutout" (claim 43), the method step of "providing a removable portion" must be shown or the features canceled from the claims. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

## Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 3. Claims 23 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The first and second surfaces being "part of a single panel" or "part of a single flexible panel" are new matter.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 22-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because it depends from a canceled claim.

In claims 22, 27, 34 and 39, the method used to seal the first to the second surface has not been defined to clearly set forth the structure of "the seal of the internal end".

Claims that have not been specifically mentioned are rejected since they depend from claims rejected under 35 U.S.C. § 112, second paragraph.

# Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 14-16, 22, 25-27, 34, 36-39 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fauci. See Figs. 3 and 4.

As a note, the first and second panels of Fauci are "sealed together" via top wall surfaces 27, 28, side walls 29, 30 and bottom wall 31. Furthermore, the column of Fauci is formed between the seams defined by walls 30, 35 sealing the first and second panels together.

Regarding method claims 15-17, 34 and 36-39, Fauci meets the structure defined by the "forming" and "presenting" steps in the claims. Therefore, the claims to the method of making the pouch are anticipated to the same degree as claimed.

- 8. Claims 1, 2, 5, 11-13, 15, 16, 19 and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hardy et al.
- 9. Claims 1, 2, 7, 8, 11-13, 15-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rinfret. See Fig. 3.
- 10. Claims 22, 24, 25, 28, 31, 32, 34, 36, 37, 40, 43, 44 and 46 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bell '177. See Figs. 6 and 7.

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As a note, the seal 73a of the internal end in Bell '177 is formed by the same method used to seal the first surface to the second surface in region 73. Furthermore, the seal 73a of the internal end in Bell '177 is formed by the same method used to seal the first surface to the second surface at seams 59, 60 to the degree that seal 73a and seams 59, 60 require heat and pressure to be formed.

## Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. Claims 1-5, 7-23, 25-30, 33-35, 37-39, 41, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell '177 in view of Hardy et al.

Bell '177 discloses the claimed device except for the column including parallel first and second seams. Hardy et al. discloses that it is known in the art to provide parallel first and second seams in an analogous column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the column of Bell '177 with the parallel first and second seams of Hardy et al., in order to guide the piercing means to the sealed point.

Regarding claims 8, 20, 27 and 39, Bell '177 and Hardy et al. disclose the claimed device, as discussed above, except for the column including a second,

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frangible seal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the column of Bell '177 with a second, frangible seal, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claims 29 and 41, Bell '177 and Hardy et al. disclose the claimed invention, as discussed above, except for the column being tapered so as to be wider at the internal end. it would have been an obvious matter of design choice to make the column of Bell '177 such that is tapered to b wider at the internal end or whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Regarding claims 7, 17, 30 and 42, Bell '177 and Hardy et al. disclose the claimed invention, as discussed above, except for the column extending beyond the seal of the internal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the seal of the internal end in the Bell '177 column such that column extends beyond the seal, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding claims 13, 19, 33 and 45, Bell '177 and Hardy et al. disclose the claimed device, as discussed above, except for the pouch having a removable portion covering the exterior end of the column. Hardy et al. discloses that it is known in the art

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to provide a removable portion over the exterior of an analogous column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the exterior end of the Bell '177 column with the removable portion of Hardy et al., in order to maintain the integrity of the column prior to receiving the piercing point.

Regarding claim 21, Bell '177 and Hardy et al. disclose the claimed invention, as discussed above, except for the panel of the compartment being formed of a multi-layer laminate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multi-layer laminate for the panel of the Bell '177 compartment, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 23 and 35, Bell '177 and Hardy et al. disclose the claimed invention, as discussed above, except for the first and second surfaces being part of a single panel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a single panel to form the first and second surfaces of Bell '177, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893).

### Response to Arguments

13. Applicant's arguments with respect to claims 1-5 and 7-46 have been considered but are most in view of the new ground(s) of rejection.

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### Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jes F. Pascua whose telephone number is 703-308-1153. The examiner can normally be reached on Mon.-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lee W. Young can be reached on 703-308-2572. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1078.

Jes F. Pascua Primary Examiner Art Unit 3727

JFP